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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,371	12/10/2001	Ian R. Reid	HO-P02194US0	6234

26271 7590 09/22/2004
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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,371	Applicant(s) REID, IAN R.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9, 11-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11-15, and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 14, 2004 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed July 14, 2004, and amendment and response to the Final Office Action (mailed September 8, 2003), filed July 14, 2004 wherein claims 1-4, 6-9, 11-15, and 17-22 have been amended.

Currently, claims 1-4, 6-9, 11-15, and 17-22 are pending in this application.

Claims 1-4, 6-9, 11-15, and 17-22 as amended now are examined on the merits herein.

Applicant's amendment filed July 14, 2004 with respect to the rejection of claims 1-4, 8-9, 12-15, and 17-22 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims (i.e., for "greater than 800 mg elemental calcium per day") of record stated in the Office Action

dated March 24, 2004 have been fully considered and found persuasive to remove the rejection since the limitation have been removed from the claims.

Applicant's amendment filed July 14, 2004, adding the limitation to the independent claims with respect to the rejection of claims 1-4, 6-9, 11-15, and 17-22 made under 35 U.S.C. 102(b) as being anticipated by Pak et al. (US 4851221) for reasons of record stated in the Office Action dated March 24, 2004 has been considered and found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-9, 11-15, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pak et al. (US 4,851,221 of record) in view of "*Calcium and Serum Cholesterol*" (Nutrition Review Vol. 25, No. 10, pp. 298 - 300, 1967; PTO-1449 submitted March 12, 2002) or Mitchell et al ("*The Effect of Oral Calcium on Cholesterol Metabolism*" PTO-1449 submitted March 12, 2002).

Pak et al. discloses that administering a calcium supplemental composition comprising calcium citrate at a dose 1g (60 meq/day) or 1.5-2.75 g calcium/day to a postmenopausal woman is useful in treating various conditions associated to a postmenopausal woman such as hypoparathyroidism, osteoporosis, bone loss, hyperphosphatemia and hypertension (see col.1 lines 49-50, 63-68; col.3 lines 42-43, 46; col.8 line 35-36; col.9 line 50-67; claim 20). The calcium citrate composition of Pak et al. is prepared from pre-mix preparation with a calcium/citrate molar ratio of 1.25 of citric acid and a calcium compound such as calcium hydroxide (see abstract, and claim 18-20).

Note that Pak et al. discloses the same effective amounts or doses of calcium citrate to be administered to the postmenopausal woman as instantly claimed.

The cited prior art does not expressly disclose measuring the high-density lipoprotein level in said woman.

The reference "*Calcium and Serum Cholesterol*" teaches that cholesterol levels are known to be measured before and at the end of calcium administration in the persons. See the first paragraph of page 299.

The reference "*The Effect of Oral Calcium on Cholesterol Metabolism*" teaches that serum cholesterol levels are known to be measured using an Auto Analyser (a known method) to test the effect of oral calcium on cholesterol metabolism. See page 916.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to measure the high-density lipoprotein level in postmenopausal woman who administering calcium citrate for increasing HDL level.

One having ordinary skill in the art at the time the invention was made would have been motivated to measure the high-density lipoprotein level in postmenopausal woman who administering calcium citrate for increasing HDL level, since measuring cholesterol levels of patients or humans before, during, and after therapeutic treatments, including with calcium, is well known in the art according the two cited references above, and is considered well within conventional skills in medical practice and pharmaceutical science, involving merely routine skill in the art.

Moreover, the patient population in Pak et al. is deemed to encompass or overlap or coincide the patient herein for increasing HDL level in plasma.

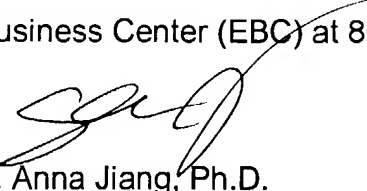
Therefore, one of ordinary skill in the art would have reasonably expected that calcium citrate would have beneficial therapeutic effects and usefulness in methods of increasing HDL level in plasma in postmenopausal women, by administering the same effective amounts of calcium citrate of Pak et al. to the same or overlapping patient population.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
September 8, 2004